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ATTACHMENT G

SUMMARY of SAFETY and EFFECTIVENESS for the DIB INFUSOR

I. Standards and Intended Use

The DIB Infusors utilize all biocompatible materials, including a medical grade silicone shaft and silicone balloon. The DIB Infusor will conform to the AMMI Draft Infusion Device Standard. The intended use of the DIB Infusor is similar to that of other legally marketed elastomeric infusion pumps.

II. Manufacturing and Testing Procedures

All manufacturing operations are performed in a class 10,000 clean room in accordance with GMP regulations. The silicone balloons are 100% tested to an internal pressure of 110±5 mmhg. Normal clinical operating pressure has been measured at approximately 70 mmhg. Full traceability of production lots will be maintained.

III. Prior In-Vitro Tests and Clinical Experience

A.) In-Vitro Tests: A Disposable Drug Infusion Balloon Catheter: A Laboratory Evaluation, Y. Susuki, M.D., et al, Department of Anesthesia, The Hospital for Sick Children and the University of Toronto, Toronto, Ontario, Canada M5G-lX8 (attached).
Dept of Biomedical Engineering, Univ of Utah, flow study on DIB model 10010

B) Clinical Experience: legally marketed DIB pumps have been used clinically in the USA for obstetrical analgesia, post operative pain, chronic pain and intravenous infusions.
Clinical Experience (outside the USA):
1) Continuous Epidural Block with a Micro-Infusion Balloon (DIB Catheter) and Patient Controlled Analgesia, Michihiro Murozono, M.D., et al, Department of Anesthesiology, Tokyo Medical School, Tokyo, Japan (attached)
2) Management of Postoperative Pain Relief, Hioko Hirota, M.D.,et al, Department of Anesthesiology, Tokyo Toshima Hospital, Tokyo, Japan (attached)
3) Ramsey Hunt Syndrome (Hunt's Neuralgia) and Continuous Infusion of Cervical Epidural Anesthesia Haruma Ikebe, M.D., et al, Department of Anesthesiology, Ooita Medical College, Tokyo, Japan (attached)
*(These publications are attached to the original Premarket Notification under **FDA file K930404**)*